

AMENDMENT AND RESPONSE

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Applicant(s): Nancy D. HANSON et al.
Serial No.: 09/814,257
Filed: 21 March 2001
For: PRIMERS FOR USE IN DETECTING BETA-LACTAMASES

5' - CAC TCA ACC CAT CCT ACC CAC C - 3' (SEQ ID NO:43); and full-length complements thereof.

Remarks

The Office Action mailed 05 May 2004 has been received and reviewed. Claims 52, 53, and 54 having been amended, claims 17 and 39-49 having been cancelled, and claims 12-16 and 51 having been indicated by the Examiner as allowable, the pending claims are claims 12-16 and 51-54.

Claim 53 has been amended to recite a method for identifying a beta-lactamase in a clinical sample that includes, *inter alia*, analyzing the separated amplified products for a region characteristic of at least one beta-lactamase selected from the group consisting of OXA-1, OXA-2, OXA-3, OXA-5, OXA-6, OXA-7, OXA-9, OXA-10, OXA-11, OXA-12, OXA-13, OXA-14, OXA-15, and combinations thereof. Support for this amendment may be found in the specification at, for example, page 13, line 30 to page 15, line 17.

Claim 54 has been amended to recite, *inter alia*, a method wherein the primers are selected from the group consisting of: 5' - CGT CGC TCA CCA TAT CTC CC - 3' (SEQ ID NO:34); 5' - CCT CTC GTG CTT TAG ACC CG - 3' (SEQ ID NO:35); 5' - CGC TGG GAA ACC TAT TCG G - 3' (SEQ ID NO:36); 5' - CTG CCA TCC AGT TTC TTC GGG - 3' (SEQ ID NO:37); 5' - GGT GGC ATT GAC AAA TTC TGG - 3' (SEQ ID NO:38); 5' - CCC ACC ATG CGA CAC CAG - 3' (SEQ ID NO:39); 5' - TGT GCA ACG CAA ATG GCA C - 3' (SEQ ID NO:40); 5' - CGA CCC CAA GTT TCC TGT AAG TG - 3' (SEQ ID NO:41); 5' - AGG CAC GAT AGT TGT GGC AGA C - 3' (SEQ ID NO:42); 5' - CAC TCA ACC CAT CCT ACC CAC C - 3' (SEQ ID NO:43); and full-length complements thereof. Support for this amendment may be found in the specification at, for example, page 13, line 30 to page 15, line 17.

Additionally, claims 52, 53, and 54 have been amended in view of the Examiner's objection thereto.

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No new matter has been added as a result of the above amendments.

Reconsideration and withdrawal of the rejections in view of the above amendments and the following comments are respectfully requested.

Allowable Claims

Applicants thank the Examiner for indicating that claims 12-16 and 51 are allowable.

Claim Objections

The Examiner objected to claims 17 and 52-54 as including an informality, asserting that the claims should include the recitation, "using a primer that is complementary to said each extension product after separation from the beta-lactamase nucleic acid;" (emphasis added).

Applicants submit that claim 17 having been cancelled renders the objection as to this claim moot. With respect to claims 52-54, Applicants disagree with the Examiner's objection and assert that these claims as previously presented were recited in proper form. However, solely to further prosecution of the present application, Applicants have amended claims 52-54 according to the Examiner's suggestion.

Reconsideration and withdrawal of the objection are, therefore, respectfully requested.

The 35 U.S.C. §112, Second Paragraph, Rejection

The Examiner rejected claims 39-48 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

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Applicants respectfully assert that the cancellation of claims 39-48 renders this rejection moot. Withdrawal of the rejection is, therefore, respectfully requested.

The 35 U.S.C. §102(a) Rejection

The Examiner rejected claims 17, 43, 53, and 54 under 35 U.S.C. §102(a) as being anticipated by Vahaboglu et al. (J. Clin. Microbiology, 36, 827-829, March 1998). Claims 17 and 43 having been cancelled renders the rejection thereto moot. With respect to claims 53 and 54, as presently amended, Applicants respectfully traverse this rejection.

Claim 53 recites a method for identifying a beta-lactamase in a clinical sample, the method including, *inter alia*, providing a pair of oligonucleotide primers specific for nucleic acid characteristic of the OXA family of beta-lactamase enzymes, annealing the primers to the beta-lactamase nucleic acid, simultaneously extending the annealed primers to synthesize an extension product, separating the amplified products and analyzing the separated amplified products for a region characteristic of at least one beta-lactamase selected from the group consisting of OXA-1, OXA-2, OXA-3, OXA-5, OXA-6, OXA-7, OXA-9, OXA-10, OXA-11, OXA-12, OXA-13, OXA-14, OXA-15, and combinations thereof, wherein when the oligonucleotide primers are specific for the OXA family beta-lactamase enzyme designated as OXA-1, the primers are selected from the group of

5' - TGT GCA ACG CAA ATG GCA C - 3' (SEQ ID NO:40);

5' - CGA CCC CAA GTT TCC TGT AAG TG - 3' (SEQ ID NO:41); and full-length complements thereof;

wherein when the oligonucleotide primers are specific for the OXA family beta-lactamase enzymes designated as OXA-5, 6, 7, 10, 11, 13, or 14, the primers are selected from the group of:

5' - GGT GGC ATT GAC AAA TTC TGG - 3' (SEQ ID NO:38);

5' - CCC ACC ATG CGA CAC CAG - 3' (SEQ ID NO:39); and full-length complements thereof;

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wherein when the oligonucleotide primers are specific for the OXA family beta-lactamase enzyme designated as OXA-9, the primers are selected from the group of;

5' - CGT CGC TCA CCA TAT CTC CC - 3' (SEQ ID NO:34);

5' - CCT CTC GTG CTT TAG ACC CG - 3' (SEQ ID NO:35); and full-length complements thereof;

wherein when the oligonucleotide primers are specific for the OXA family beta-lactamase enzyme designated as OXA-12, the primers are selected from the group of:

5' - CGC TGG GAA ACC TAT TCG G - 3' (SEQ ID NO:36);

5' - CTG CCA TCC AGT TTC TTC GGG - 3' (SEQ ID NO:37); and full-length complements thereof;

and wherein when the oligonucleotide primers are specific for the OXA family beta-lactamase enzyme designated as OXA-2, 3, or 15, the primers are selected from the group of:

5' - AGG CAC GAT AGT TGT GGC AGA C - 3' (SEQ ID NO:42);

5' - CAC TCA ACC CAT CCT ACC CAC C - 3' (SEQ ID NO:43); and full-length complements thereof.

Applicants respectfully assert that Vahaboglu et al. fail to teach Applicants' method for identifying a beta-lactamase wherein the separated amplified products are analyzed for a region characteristic of at least one beta-lactamase selected from OXA1-3, OXA-5-7, OXA 9-15, and combinations thereof using the primers designated as SEQ ID Nos. 34-43, as recited in claim 53, as amended.

Additionally, claim 54, as amended, recites a method for identifying a beta-lactamase in a clinical sample, the method including: providing a pair of oligonucleotide primers wherein, *inter alia*, the primers are selected from the group of: 5' - CGT CGC TCA CCA TAT CTC CC - 3' (SEQ ID NO:34); 5' - CCT CTC GTG CTT TAG ACC CG - 3' (SEQ ID NO:35); 5' - CGC TGG GAA ACC TAT TCG G - 3' (SEQ ID NO:36); 5' - CTG CCA TCC AGT TTC TTC GGG - 3' (SEQ ID NO:37); 5' - GGT GGC ATT GAC AAA TTC TGG - 3' (SEQ ID NO:38); 5' -

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CCC ACC ATG CGA CAC CAG - 3' (SEQ ID NO:39); 5' - TGT GCA ACG CAA ATG GCA C - 3' (SEQ ID NO:40); 5' - CGA CCC CAA GTT TCC TGT AAG TG - 3' (SEQ ID NO:41); 5' - AGG CAC GAT AGT TGT GGC AGA C - 3' (SEQ ID NO:42); 5' - CAC TCA ACC CAT CCT ACC CAC C - 3' (SEQ ID NO:43); and full-length complements thereof. Applicants assert that Vahaboglu et al. also fail to teach Applicants' claim 54, as amended.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. §102(a) of claims 17, 43, 53, and 54, as amended.

The 35 U.S.C. §103(a) Rejections

The Examiner rejected claim 39 under 35 U.S.C. §103(a) as being unpatentable over Vahaboglu et al. (March 1998) as applied to claims 17, 43, 53, and 54, and further in view of Tolmasky, (Plasmid, 24, 218-226, 1990) as evidenced by Tolmasky et al., (Plasmid, 29, 31-40, 1993).

The Examiner rejected claim 41 under 35 U.S.C. §103(a) as being unpatentable over Vahaboglu et al. (March 1998) as applied to claims 17, 43, 53, and 54, and further in view of Rasmussen et al. (Antimicrobial Agents and Chemotherapy, 38, 2078-2085, September 1994) as evidenced by Alksne et al., (Journal of Bacteriology, 179, 2006-2013, March 1997).

The Examiner rejected claim 47 under 35 U.S.C. §103(a) as being unpatentable over Vahaboglu et al., (March 1998) as applied to claims 17, 43, 53, and 54, and further in view of Danel et al., (Antimicrobial Agents and Chemotherapy, 41, 785-790, April 1997).

The Examiner rejected claim 49 under 35 U.S.C. §103(a) as being unpatentable over Vahaboglu et al., (March 1998) as applied to claims 17, 43, 53, and 54, and further in view of Fluit et al. (WO 91/08305).

Applicants respectfully assert that the cancellation of claims 39, 41, 47, and 49 renders the rejections of these claims moot. Withdrawal of the rejections is, therefore, respectfully requested.

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Summary

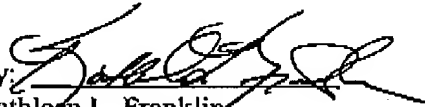
It is respectfully submitted that the pending claims 12-16 and 51-54 are in condition for allowance and notification to that effect is respectfully requested.

The Examiner is invited to contact Applicants' Representatives, at the below-listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted for
HANSON et al.,

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CERTIFICATE UNDER 37 CFR §1.8:

The undersigned hereby certifies that the Transmittal Letter and the paper(s), as described hereinabove, are being transmitted by facsimile in accordance with 37 CFR §1.6(d) to the Patent and Trademark Office, addressed to Commissioner for Patents, Mail Stop AF, P.O. Box 1450, Alexandria, VA 22313-1450, on this 5th day of October, 2004, at 2:05 pm (Central Time).

By: 
Name: Kathleen L. Franklin